ANCILLARY STUDIES IN CONJUNCTION WITH SHOW TRIAL

Release Date: August 2, 2000

RFA: DK-00-017

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
http://www.niddk.nih.gov/
National Heart, Lung, and Blood Institute (NHLBI)
http://www.nhlbi.nih.gov/index.html
National Institute of Nursing Research (NINR)
http://www.nih.gov/ninr/
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
http://www.nih.gov/niams/
National Institute of Dental and Craniofacial Research (NIDCR)
http://www.nidr.nih.gov/

Letter of Intent Receipt Date: September 15, 2000
Application Receipt Date: November 16, 2000

PURPOSE

The Study of Health Outcomes of Weight-Loss (SHOW) clinical trial will investigate the health effects of interventions designed to produce long-term weight loss in overweight and obese individuals with type 2 diabetes. During the course of the trial, SHOW participants will be carefully assessed for a number of metabolic, behavioral, physiological and pathological characteristics and for changes in these characteristics. The availability of such a well-described and diverse population of obese individuals with type 2 diabetes undergoing long-term weight loss interventions is unique.

The purpose of this initiative is to solicit applications for a range of basic, clinical, and behavioral ancillary research studies that do not duplicate or interfere with the primary and secondary aims of SHOW. These ancillary studies can enhance investigation of the response of the various participants' characteristics to weight loss interventions, the impact of weight loss interventions on obesity-related comorbid conditions, the relationship of genetic factors to these responses, and the psychosocial correlates or determinants of behavior change. In addition, the SHOW cohort may offer the opportunity for ancillary studies to examine the incidence or progression of obesity-

related pathological conditions in populations in which additional study is needed, to identify biomarkers for disease risk, and to investigate relatively rare or understudied obesity-related conditions in this large sample. The SHOW trial also will offer the opportunity for investigations requiring a longer follow-up period than has been available in the past. The Institutions sponsoring this RFA intend to fund a broad range of studies in categories such as those described under Research Objectives.

HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), Ancillary Studies in Conjunction with SHOW Trial, is related to three of the objectives for improving health: #5, Diabetes; #12 Heart Disease; and #19, Nutrition and Overweight. Potential applicants may obtain a copy of "Healthy People 2010" at: http://www.health.gov/healthypeople/default.htm

ELIGIBILITY REQUIREMENTS

All applicants to this RFA must complete a series of steps to obtain preliminary approval from the SHOW Substudies and Ancillary Studies (SAS) Committee for the concept they propose. These steps are delineated in SPECIAL REQUIREMENTS (see below). The purpose of the approval process is to ensure that proposed studies do not place an undue burden upon SHOW participants, that they are feasible within the context of SHOW, and are consistent with SHOW goals and priorities. If the steps in the approval process are not followed, the application will be considered non-responsive to the RFA and will be returned to the investigator.

Applicants do not need to be associated currently with a SHOW Center. However, all applicants, including those who already are part of a SHOW center, must obtain written agreement from at least one SHOW Center Principal Investigator to collaborate on the application, as described in SPECIAL REQUIREMENTS.

To be eligible for this RFA, applicants must affirm in writing their willingness to abide by all SHOW policies. These policies will be posted at the SHOW Website: http://show.phs.wfubmc.edu/ under Information as they become available. The SHOW Ancillary Study Policy states that the Ancillary Study Principal Investigator will be given the first opportunity to analyze, present and publish data collected for the specific aims of the ancillary study.

Note that access to study data and timing of publication of study data are subject to the SHOW publications policies. It is possible that in some cases this may result in delayed publication of results of the ancillary studies. In addition, all ancillary study data will become part of the SHOW collaborative database according to SHOW policies.

Applications may be submitted by domestic and foreign for-profit and nonprofit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign organizations are eligible to apply subject to the same constraints concerning collaboration with one or more SHOW investigators cited above. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) research project grant (R01) award mechanism. Except as otherwise stated in this announcement, awards will be administered under NIH grants policy as stated in the NIH Grants Policy Statement.

This RFA is a one-time solicitation. The anticipated award date is July 1, 2001.

Subsequent to peer review, NIH will consult with the SHOW Steering Committee to develop a list of those applications that possess not only high scientific merit as judged by NIH peer review, but also comprise a broad range of research topics consistent with the aims of SHOW and do not in the aggregate place too great a burden on SHOW participants or centers. NOTE: While scientific merit will be a major factor in funding decisions made by the sponsoring Institutes, the funding plan also must be acceptable in the context of burden to SHOW. Thus applications may not be funded in strict priority score order.

Responsibility for the planning, direction, and execution of the proposed project will be primarily that of the applicant. However, applicants must work collaboratively with SHOW centers to ensure that the SHOW design and SHOW policies are not compromised.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from either the GCRC program director or principal investigator should be included with the application.

FUNDS AVAILABLE

The NIDDK intends to commit approximately $2,000,000 in FY 2001 to fund approximately 6 to 10 new grants in response to this RFA.

In addition:
o NHLBI will fund meritorious applications that are relevant to its mission of investigations related to heart, lung, and blood diseases and sleep disorders. o NINR also will consider for funding those meritorious applications that are relevant to its mission of investigations related to nursing interventions and patient outcomes or to basic research.
o NIAMS will consider for funding those meritorious applications that are relevant to its mission related to osteoarthritis and osteoporosis.
o NIDCR will consider funding meritorious applications that propose research to investigate the effects of weight loss on oral and craniofacial health and diseases (for example, periodontitis).

Because the nature and scope of the research proposed may vary, it is anticipated that the size of the awards will vary considerably. An applicant may request a project period of up to five years and a budget for direct costs of up to $500,000 per year, including Facilities and Administrative (F&A) costs on consortium arrangements. However, smaller grant applications are encouraged, in keeping with the intent of the NIH to fund a broad range of applications.

Although the financial plans of the NIDDK provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of applications of outstanding scientific and technical merit. At this time, it is not known if competing renewal applications will be accepted.

RESEARCH OBJECTIVES

Background

Numerous studies have demonstrated the beneficial impact of short-term weight loss on risk factors such as dyslipidemia, hyperinsulinemia, hypertension, and elevated plasma glucose. Based on long-term epidemiological evidence of the health hazards of overweight and obesity and on shorter term clinical trial evidence, public health policy recommends weight loss for obese individuals (BMI 30 or above) or overweight individuals (BMI 25.0 – 29.9) with one or more additional comorbidities (NHLBI and NIDDK: Clinical Guidelines on the Identification, Evaluation,

and Treatment of Overweight and Obesity in Adults, 1998; available at http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm.)

Currently in the U.S. 40% of women and 25% of men are attempting to lose weight, using a variety of means. Despite this fact, few studies have examined the health effects of intentional weight loss over a period greater than one year and very few beyond four years. Moreover, several major observational studies show a significant association between weight loss and mortality that persists even after attempts to correct for confounding factors (e.g., smoking or pre-existing illness). However, most of these observational studies are unable to distinguish between voluntary and involuntary weight loss. SHOW has been undertaken by the NIDDK with support from the National Heart, Lung and Blood Institute, the National Institute of Nursing Research, the Centers for Disease Control and Prevention, the Office of Research on Women's Health and the Office of Research on Minority Health to address this important public health question.

Sixteen Clinical Centers throughout the United States, with coordination support from a Coordinating Center at Wake Forest University, will conduct SHOW. Please see the SHOW website for listing of Centers at: http://show.phs.wfubmc.edu/ under “Information.”

Summary of Current Design of SHOW:

The following summary puts forward those elements of the SHOW design that have been approved by the Steering Committee at the time of issuance of this RFA.

SHOW plans to recruit 6000 overweight and obese individuals with type 2 diabetes from diverse backgrounds over a three-year period. While the exact length of the SHOW interventions has not yet been finalized, all participants will receive an intervention of least four years duration. All participants will be followed for an additional period of 4.5 years minimum to assess the occurrence of cardiovascular events. One-half of the participants recruited to the study will be randomly assigned to an active behavioral weight loss intervention including group and individual sessions and the potential use of obesity medications as part of a toolbox approach. The other half of SHOW participants will be assigned to community care. The primary outcome of the SHOW trial will be cardiovascular events (combined incidence of fatal and non-fatal myocardial infarction, fatal and non-fatal stroke, and cardiovascular-related death). It is anticipated that SHOW will exclude individuals with CVD at baseline. Remaining issues relating to eligibility criteria, details of intervention, etc. are under discussion.

Secondary outcomes have not been voted upon at the time of publication of this RFA; however, it is likely that ultrasound measures of carotid intimal-medial thickness will be used to assess progression of atherosclerosis in a subset of SHOW participants. It also is likely that a measure of body composition, such as DEXA and/or computed tomography, will be included on a subset of participants.

Applicants to this RFA should not propose investigations that duplicate or interfere with the primary and secondary outcomes included in SHOW.

NOTE: Investigators are encouraged to remain in close contact with the SHOW co-investigator on their applications in order to ensure that they have the latest information available on the status of the SHOW design and the outcome measures to be included in SHOW. In addition, communications with NIH program staff and with the SHOW Substudies and Ancillary Studies (SAS) Committee, as described under SPECIAL REQUIREMENTS can provide up-to-date information.

Scope

The purpose of this initiative is to solicit applications for a range of basic, clinical, and behavioral ancillary research studies that are consistent with the aims of SHOW. These ancillary studies can enhance investigation of the response of the various participants' characteristics to weight loss interventions, the impact of weight loss interventions on obesity-related comorbid conditions, the relationship of genetic factors to these responses, and the psychosocial correlates or determinants of behavior change. In addition, the SHOW cohort may offer the opportunity for ancillary studies to examine the incidence or progression of obesity-related pathological conditions in populations in which additional study is needed, to identify biomarkers for disease risk, and to investigate relatively rare or understudied obesity-related conditions in this large sample. The SHOW trial also will offer the opportunity for investigations requiring a longer follow-up period than has been available in the past. The Institutions sponsoring this RFA intend to fund a broad range of studies in categories such as those described under Research Objectives.

Studies may be proposed on the entire population sample or on a subset defined by variables such as: age, gender, ethnicity/race, clinic, or socioeconomic status. Applicants are encouraged to propose studies that investigate health disparities in these groups.

Examples of research topics considered responsive to this RFA include, but are not limited to:

Genetic Studies, such as:
o Mutation and polymorphism detection
o Genotype/phenotype association studies

Metabolic/Physiological studies, such as:
o Substrate utilization as a function of treatment/weight loss
o Lipid metabolism and kinetics
o Insulin action and glucose disposal
o Modulation of inflammatory markers/mediators
o Left ventricular mass or function
o Effects of hormonal status on response to intervention

Natural History of Comorbid Conditions or Impact of Interventions on Conditions, such as:
o Sleep apnea
o Diabetic eye disease
o Urologic and renal disease
o Non-alcoholic steatohepatitis
o Osteoporosis/bone density
o Osteoarthritis
o Periodontal disease
o Subclinical cardiovascular disease measures such as: left ventricular mass or dysfunction, coronary calcification, ankle-brachial index
o New cardiovascular disease risk factors such as homocysteine, thrombotic factors, cardiovascular reactivity, endothelial function

Psychosocial, Behavioral, and Economic Correlates or Predictors in research areas such as:
o Health and/or physiological outcomes
o Long term weight maintenance
o Eating behaviors
o Psychopathology
o Diet and physical activity changes
o Adherence to medications

Measures and Methodology Studies, such as:
o Body composition measures other than total fat and fat free mass, including organ and elemental measures
o Objective measures of diet or physical activity complementary to those proposed for SHOW

o Measures of subclinical disease
o Measures of medication adherence

NOTE: The following types of applications are NOT acceptable under this RFA:
o Ancillary studies that propose alterations to the basic SHOW trial design.
o Ancillary studies comparing surgical patients to those in SHOW should not be submitted to this RFA. The NIDDK is working with the surgical and obesity research communities to develop a specific initiative relating to this question.
o Development of resources that do not address a research question (e.g., DNA bank).
o Studies in which the specific aims duplicate or interfere with the specific aims of SHOW.

NOTE: Applicants should note that awards are unlikely to be made in time to collect data from the beginning of recruitment, currently projected for Spring, 2001. However, it is anticipated that ancillary studies will be able to start within the first six months of recruitment.

SPECIAL REQUIREMENTS

In addition to the general requirements of NIH research project grant applications, applicants to this RFA must provide the following with the application:

1) Documentation of Collaboration with SHOW Clinical Center(s).

An applicant must establish collaborations with the Principal Investigators of each SHOW Clinical Center that would participate in the applicant's proposed research. These collaborations should be documented by a letter from each SHOW Clinical Center Principal Investigator involved, indicating that the investigator is willing to collaborate with the applicant as necessary to conduct the proposed study at his/her SHOW Center. Even if a study requires no patient contact or direct involvement with a SHOW Center (e.g. analysis of centrally banked specimens), at least one SHOW PI must document willingness to collaborate. SHOW Principal Investigators and Clinical Centers are listed at the website for SHOW: http://show.phs.wfubmc.edu/ under “Information.”

2) Documentation of Preliminary Approval from the SHOW Substudies and Ancillary Studies (SAS) Committee.

Before applying to this RFA, applicants must electronically submit a form (entitled Preliminary Proposal for SHOW Ancillary Study) to the Coordinating Center, which will forward the form to the SAS Committee. This form is available on the SHOW website at: http://show.phs.wfubmc.edu/

under Information. This form will help to describe the participant burden, including clinic time, time to fill out questionnaires, amounts of specimens to be collected, etc. In order to allow time for reviewing the Preliminary Proposal and responding to potential applicants, the completed form should be submitted electronically to the SHOW Coordinating Center not later than September 15, 2000. In addition, applicants are encouraged to contact Barbara Harrison (contact information provided below under INQUIRIES) to facilitate contacts with the SHOW SAS Committee and to ensure a clear understanding of the ancillary studies submission and review process. Note: if you experience difficulties with the form, you may call or email Terri Windham of the Coordinating Center at 336-716-6939, twindham@wfubmc.edu to obtain assistance.

Within two to four weeks after the completed "Preliminary Proposal for SHOW Ancillary Study" form is submitted, the SAS Committee will respond to the applicant (with a copy to the NIDDK) indicating either that it considers the proposal to be potentially acceptable as a SHOW ancillary study or that the proposal is unacceptable as a SHOW ancillary study. The SAS potential acceptability letter will indicate that the study is technically and administratively feasible as an ancillary study, is compatible with the SHOW protocol, is consistent with overall aims of SHOW, and by itself will not add undue burden to the SHOW participants or Clinical Centers. The letter does NOT indicate review of scientific merit.

The SHOW SAS committee letter indicating potential acceptability as an ancillary study must be submitted with the application to this RFA. Without preliminary approval from the SAS Committee, the application will be considered non-responsive to the RFA and will be returned to the investigator.

NOTE: The SAS Committee letter indicating potential acceptability does not guarantee that the proposed study will be acceptable if it receives a meritorious score. Final approval of a SHOW ancillary study application will depend upon the aggregate burden to SHOW participants and Centers from all ancillary studies under consideration as well as the ancillary study's relationship to SHOW aims and the priority of the NIH to fund a range of scientifically meritorious research topics.

3) Documentation of Collaboration with the SHOW Coordinating Center

Applicants whose proposals are considered potentially acceptable by the SAS Committee will be asked to contact the SHOW Coordinating Center to provide additional information, since most ancillary studies will require access to and/or processing of SHOW data. The purpose of this contact with the Coordinating Center is to ensure that the necessary resources are already

available at the Coordinating Center (in the case of minimal requirements) or that they are budgeted in the ancillary study application as a subcontract (in the case of more extensive requirements) and that data entry plans will be coordinated.

After necessary contacts have been made with the Coordinating Center, a letter will be provided by the Coordinating Center to the applicant indicating its ability and willingness to provide the support required by the applicant. THIS LETTER MUST BE SUBMITTED WITH THE APPLICATION TO THIS RFA. The applicant should contact the Coordinating Center by October 16, 2000 to ensure receiving this required letter before the RFA receipt date.

4) Shorter Research Plan

Instead of the normal 25-page length, the research plan in this ancillary study application should be limited to 15 pages, excluding references. It should be submitted on the standard PHS 398 form. As usual, the research plan includes specific aims, background and significance, preliminary studies, and research design and methods (Sections A to D.). Note that it is not necessary to describe the SHOW trial in the application. Statements and documentation required in this SPECIAL REQUIREMENTS section are not included in the 15-page limit.

5) Statement of Need for Access to SHOW

The applicant should explicitly address any unique aspects of SHOW as a vehicle for conduct of the proposed ancillary study. Applicants also are encouraged to address the overall burden to SHOW participants posed by their projects.

6) Documentation of Willingness to Participate in a Collaborative Study

All applicants must indicate in writing their willingness to participate collaboratively with the SHOW Steering Committee as well as the individual Centers proposed in the application to conduct the proposed ancillary study; to communicate results in a manner consistent with SHOW procedures; and to be willing to abide by all SHOW policies. Note that access to study data and timing of publication of study data are subject to the SHOW publications policies. It is possible that in some cases, these policies may result in delayed publication of ancillary studies results.

Applicants are encouraged to work with other applicants who may be considering similar applications to SHOW. Please contact Barbara Harrison (contact information under INQUIRIES

below) to discuss potential for collaborations with other investigators considering similar research topics. The applicant should plan to attend one SHOW meeting per year to consult with the SAS Committee and the Steering Committee, and should include funds for this travel in the application ($1,500 per meeting may be assumed as the cost for travel).

7) Documentation of Willingness to Submit All Data.

Grantees are required to submit all data collected under the ancillary study to the SHOW Coordinating Center. These data will become part of the SHOW Collaborative database, consistent with SHOW policies. The applicant's budget should include resources to provide these data, accompanied by relevant forms and documentation, to the Coordinating Center in electronic form.

8) Documentation of Willingness to Share Applications with the SHOW SAS Committee and Steering Committee

Applicants must include in the application a written statement indicating their willingness to allow their application to be shared with the SHOW SAS Committee and Steering Committee if the initial peer review indicates that the application is potentially fundable. Failure to include such a statement may lead to rejection of the application as non-responsive to this RFA.

9) Collection of Biological Specimens

A variety of biological specimens (e.g. serum, DNA) from SHOW participants will be stored centrally; however, at the time of issuing this RFA, it is not yet known which of these materials will be available for ancillary studies. Thus each applicant should include appropriate resources in the budget to collect and process the biological specimens that are required for the proposed research.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which was published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide For Grants and Contracts, Vol. 23, No. 11, March 18, 1994, available on the web at: http://grants.nih.gov/grants/guide/notice-files/not94-100.html

URLs IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

LETTER OF INTENT

Prospective applicants are asked to submit, by September 15, 2000, a letter of intent that includes a descriptive title of the proposed research, name, address, and telephone number of the Principal Investigator, identities of other key personnel and participating institutions, and number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information it contains allows the NIDDK staff to estimate the potential review workload and avoid conflict of interest in the review. The letter of intent is to be sent to:

Chief, Review Branch
Division of Extramural Activities
National Institute of Diabetes, Digestive, and Kidney Diseases
Room 653, MSC 5452
6707 Democracy Boulevard
Bethesda, Maryland 20892-5452 (for courier service use 20817)
Telephone: (301) 594-8885
Fax: (301) 480-3505
Email: hagana@extra.niddk.nih.gov

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301-435-0714, email: GrantsInfo@nih.gov.

NOTE: The PHS 398 form should be used, but research plans should be limited to 15 pages in length, instead of the 25 pages stipulated in the PHS 398.

Budget Instructions

Applications submitted in response to this RFA should not use the modular grant format. Budgets should be prepared according to the standard PHS form 398 instructions.

Additional Budget Information Required Of All Applicants To This RFA:

o If significant Coordinating Center resources will be needed, applicants should discuss the details with the SHOW Coordinating Center and include a subcontract to the Coordinating Center to provide necessary funding for these resources.
o Applicants should include funds to provide data, forms and documentation to the SHOW Coordinating Center in electronic form.
o Applicants should include travel funds to attend one SHOW Steering Committee meeting per year (applicant may assume $1,500 as cost for this travel).
o Applicants should not assume that SHOW staff will be available to assist in the conduct of proposed studies. Budgets should include additional staffing and/or resources needed to conduct the proposed studies in conjunction with SHOW.
o Applicants should budget for collecting and processing any required biological specimens. If these materials become available centrally, budgets will be adjusted accordingly.

The RFA label available in the PHS 398 (rev. 4/98) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked.

The sample RFA label available at:

http://grants.nih.gov/grants/funding/phs398/label-bk.pdf has been modified to allow for this change. Please note this is in pdf format.

Submit a signed, typewritten original of the application, including the Checklist, and three signed photocopies, in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040 - MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 for express/courier service

At time of submission, two additional copies of the application must be sent to:

Chief, Review Branch
Division of Extramural Activities, NIDDK
6707 Democracy Blvd., Rm 660, MSC 5452
Bethesda, MD 20892-5452
Bethesda, MD 20817 for express/courier service

Applications must be received by the application receipt date listed in the heading of the RFA. If an application is received after that date, it will be returned to the applicant without review. Supplemental documents containing significant revision or additions will not be accepted, unless applicants are notified by the Scientific Review Administrator.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications previously reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the NIDDK. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration.

NOTE: APPLICATIONS MUST MEET THE SPECIAL REQUIREMENTS CITED IN THIS RFA TO BE JUDGED RESPONSIVE.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIDDK in accordance with the review criteria stated below. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed, assigned a priority score, and receive a second level review by the National Diabetes and Digestive and Kidney Diseases Advisory Council.

In addition to the second level review by Council, the SHOW Steering Committee will recommend to the sponsoring Institutes a list of those applications that comprise a broad range of research topics consistent with the aims of SHOW and do not in the aggregate place too great a burden on SHOW participants or centers. NOTE: While scientific merit will be a major factor in funding decisions by the sponsoring Institutes, the funding plan also must be acceptable in the context of burden to SHOW. Thus, applications may not be funded in strict priority score order.

Review Criteria:

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

(1) Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

(3) Innovation: Does the project employ novel concepts, approaches or method?
Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

o Adequacy of plans to include both genders, minorities and their subgroups as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.
o The reasonableness of the proposed budget and duration to the proposed research.
o The adequacy of the proposed protection of humans, animals, or the environment, to the extent that they may be adversely affected by the project proposed in the application.
o Availability of special opportunities for furthering research programs through the use of unusual talent resources, populations, or environmental conditions in other countries which are not readily available in the United States or which provide augmentation of existing U.S. resources.

Schedule:

Submit “Preliminary Proposal for SHOW Ancillary Study” form to Coordinating Center not later than September 15, 2000
Submit Letter of Intent: September 15, 2000
Discuss data requirements with Coordinating Center: not later than October 16, 2000
Application Receipt Date: November 16, 2000
Peer Review Date: February-April, 2001
Council Review: May, 2001
Earliest Anticipated Start Date: July 01, 2001

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

o Scientific merit as determined by NIH peer review
o Availability of funds
o Overall programmatic balance. A broad range of research topics to be investigated by the ancillary studies is sought.
o Overall burden to SHOW participants
o Overall burden to staff or materials required at SHOW centers
o Uniqueness of the SHOW population sample for the conduct of the proposed ancillary study
o Willingness to collaborate with other SHOW investigators

INQUIRIES

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Direct inquiries regarding programmatic issues to:

Barbara Harrison, M.S.
Division of Digestive Diseases and Nutrition
NIDDK
6707 Democracy Blvd.
Room 661, MSC 5450
Bethesda, MD 20892-5450
Telephone: (301) 594-8858
FAX: (301) 480-8300
E-mail: HarrisonB@extra.niddk.nih.gov

Eva Obarzanek, Ph.D., R.D.
Division of Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
6701 Rockledge Drive
Room 8136, MSC 7936
Bethesda, MD 20892-7936
Telephone: (301) 435-0377
FAX: (301) 480-1669
Email: ObarzanE@nhlbi.nih.gov

Nell Armstrong, Ph.D., RN
Program Director
NINR
Building 45, Room 3AN12
Bethesda MD 20892-6300
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FAX: (301) 480-8260
Email: nell_armstrong@nih.gov

Joan A. McGowan, Ph.D.
Director, Musculoskeletal Diseases Branch
NIAMS
Natcher Building, Room 5AS-43E
Bethesda, Md. 20892-6500
Phone: (301) 594-5055
FAX: (301) 480-4543
E-mail: joan_mcgowan@nih.gov

Maryann Redford, Ph.D.
Division of Extramural Research
NIDCR
45 Center Drive, Room 4 AN-24B, MSC 6402
Bethesda, MD 20892-6402
Telephone: (301) 594-5588
FAX: (301) 480-8318
Email: Maryann.Redford@nih.gov

Note that potential applicants to this RFA also are required to contact the SHOW SAS Committee either through Barbara Harrison or directly through the SHOW website at: http://show.phs.wfubmc.edu/ under Information.

Direct inquiries regarding fiscal matters to:

Sharon Bourque
Division of Extramural Activities
NIDDK
6707 Democracy Blvd., Room 612

Bethesda, MD 20892-5456
Telephone: (301) 594-8846
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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.848, 93.837, No. 93.361, No. 93.121, and No. 93.846. Awards are under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under NIH grants policies and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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